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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,354	03/08/2004	Patrick Koch	0701.125F	2285

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EXAMINER	
KRASS, FREDERICK F	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/796,354	KOCH ET AL.	
	Examiner	Art Unit	
	Frederick F. Krass	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/8/04; 7/19/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claim Informalities

The following corrections should be made to place the claims in better form:

Claims 8, 11, 15 and 18, in each instance each claim should be amended to end in one period, not two.

Anticipation Rejection

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claim 19 is rejected under 35 U.S.C. 102(e) as being anticipated by Larsson et al (USP 5,948,789).

The prior art discloses the preparation of S(-) rabeprazole in working example 25 (at column 19), where 1.62 grams (a therapeutically effective amount, especially where used in a divided daily dose, or in a laboratory mouse model, at the very least) is recovered in aqueous phase (a pharmaceutically acceptable carrier suitable for oral therapy).

Obviousness Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1) Claims 1-3, 5-15, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Souda et al (USP 5,045,552) in view of Nochi et al.

The primary reference teaches orally administrating (by capsule or tablet) racemic rabeprazole (compound 19 in Table I at column 13) to treat conditions caused or contributed to by gastric hypersecretion, such as ulcers (see specifically column 1, lines 15-60 and the passage spanning column 15, line 1 to column 16, line 20). The dosages used are equivalent to those claimed by Applicant (column 16, lines 21-39). The primary reference differs from instant claims 2 and 12 insofar as it does not disclose the treatment of GI reflux disease or Zollinger-Ellison Syndrome *ipsissima verba*, but it is well-known in the art that ulcer-treating agents which act by suppressing gastric hypersecretion (i.e., proton pump inhibitors) are also useful for treating related conditions such as GI reflux disease and Zollinger-Ellison

Syndrome. Accordingly, since the same fundamental etiology is involved in each case, the use of the prior art compounds to treat those conditions would have been self- evident therefrom.

The primary reference is not anticipatory of the instant claims insofar as, although it suggests the use of stereoisomers at column 6, lines 5-9, it does not specifically disclose isolated stereoisomers, e.g. in the form of a preferred embodiment or working example.

In general, stereoisomers/optical isomers are obvious from racemic mixtures. As legal authority the examiner cites *In re Adamson and Duffin*, 125 USPQ 233. The case sets forth the standard of patentability with regard to stereoisomers as follows:

i) The existence of a racemate is, in and of itself, sufficient to render obvious any individual stereoisomers isolated therefrom; no express suggestion of isomer separation is needed. See the first paragraph on page 235.

ii) One skilled in the art expects that individual stereoisomers will differ significantly in physiological/pharmacological activity and toxicity, because living systems are chiral and thus preferentially process certain stereochemical configurations over others. See page 234, the third full paragraph and page 235, the fifth full paragraph on the page.

See also *In re Anthony*, 162 USPQ 595 and *In re May and Eddy*, 192 USPQ 601.

The isolated (S) and (R) stereoisomers of rabeprazole are known, as is illustrated by the secondary reference, which differs from the instant claims insofar as it chromatographically separates the isomers, but does not further use them in additional studies.

It would have been obvious to have orally administered the isolated (S) isomer of rabeprazole, which is known from the secondary reference disclosure, to treat conditions caused by gastric hypersecretion, including ulcers, GI reflux disease and Zollinger-Ellison Syndrome, motivated the

reasonable expectation of success for such treatment provided by the primary reference, and consonant with the reasoning of the above-cited precedent.

2) Claims 4 and 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hasselkus (USP 5,714,505) in view of Nochi et al.

The primary reference teaches orally administering capsules containing 1 to 100mg (column 2, lines 31-53) of a proton pump inhibitor, including racemic rabeprazole (the fifth compound from the top of column 3, at line 40), to treat psoriasis.

The secondary reference has been discussed in subsection "1)" above. Again, It would have been obvious to have orally administered the isolated (S) isomer of rabeprazole, which is known from the secondary reference disclosure, to treat psoriasis, motivated the reasonable expectation of success for such treatment provided by the primary reference, and consonant with the reasoning of the precedent previously cited and discussed in subsection "1)" above.

3) Claims 1-3, 5-15 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Larsson et al in view of Souda et al.

The primary reference has been discussed previously and differs from the instant claims in that, although it suggests the use of "one of the single enantiomers" of rabeprazole (claim 31) "for the treatment of gastrointestinal diseases" claim 35, it never specifically discloses the use of S(-)rabeprazole to treat any specific condition.

The secondary reference has been discussed in subsection "1)" above and teaches orally administrating (by capsule or tablet) racemic rabeprazole (compound 19 in Table I at column 13) to treat conditions caused or contributed to by gastric hypersecretion, such as ulcers (see specifically column 1, lines 15-60 and the passage spanning column 15, line 1 to column 16, line 20). The dosages used are equivalent to those claimed by Applicant (column 16, lines 21-39). It differs from instant claims 2 and 12 insofar as it does not disclose the treatment of GI reflux disease or Zollinger-Ellison Syndrome *ipsissima verba*, but it is well-known in the art that ulcer-treating agents which act by suppressing gastric

hypersecretion (i.e., proton pump inhibitors) are also useful for treating related conditions such as GI reflux disease and Zollinger-Ellison Syndrome. Accordingly, since the same fundamental etiology is involved in each case, the use of the prior art compounds to treat those conditions would have been self-evident therefrom.

It would have been obvious to have orally administered the isolated (S) isomer of rabeprazole, disclosed by the primary reference, to treat conditions caused by gastric hypersecretion, including ulcers, GI reflux disease and Zollinger-Ellison Syndrome, motivated the reasonable expectation of success for such treatment provided by the secondary reference, and consonant with the reasoning of the precedent previously cited and discussed in subsection "1)" above.

Action is Final

This is a continuation of applicant's earlier Application No. 10/263,558. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Krass whose telephone number is 571-272-0580. The examiner's schedule is as follows:

Monday: 10:30AM- 7PM;
Tuesday: 10:30AM - 7PM;
Wednesday: off;
Thursday: 10:30AM- 7PM; and
Friday: 10:30AM-7PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass
Primary Examiner
Art Unit 1614